REMARKS

Claims 59-80 are pending in this application. Claims 66-80 are canceled herein without prejudice to expedite prosecution. Claims 59, 64, and 65 are amended herein for clarity. Support for these amendments can be found in the original claim language and throughout the specification, as set forth below. It is believed that these amendments add no new matter. In light of these amendments and the following remarks, applicants respectfully request reconsideration of this application, entry of these amendments and allowance of the pending claims.

Applicants gratefully acknowledge the removal of the rejections under 35 U.S.C. §101, under 35 U.S.C. § 112 enablement, and under 35 U.S.C. § 102 over Tanaka.

The amendments to the claims are believed to address and overcome the rejection under 35 U.S.C. §112, indefiniteness. Applicants below address the only other remaining rejections from the August 26, 2003 Office Action.

35 U.S.C. § 112, first paragraph

Claims 59-65 and 77-80 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. Specifically, the Office Action states the phrases "embryo that develops and hatches in the shell" in claims 59, 64 and 65; "shell that formed around a female pronucleus that developed into the embryo" in claims 59 and 64; "shell that formed around a female pronucleus that developed into the zygote" in claim 65; "fertilizing an ovum by delivering a sperm sample comprising avian sperm in a physiologically acceptable carrier into the egg and incubating the egg" in claim 77; and "shell that formed around the yolk during shell membrane deposition and calcification" in claim 80 are new matter.

Claims 77-80 are canceled herein without prejudice, thereby rendering moot the rejections as applied to these claims. Thus, applicants request withdrawal of these rejections.

Claims 59, 64 and 65 are amended herein by deleting the problematic language and substituting therefor language that more clearly recites the development of the shell in reference

to the female pronucleus which it encloses. Specifically, the phrase "the shell is deposited around a female pronucleus before the female pronucleus joins a male pronucleus" points out that the female pronucleus is enclosed within a calcified shell at the time of oviposition from the bird's vagina before being contacted with a male pronucleus after oviposition. The joining of a female pronucleus and a male pronucleus after oviposition leads to the development of a zygote and embryo. See in the specification page 5, lines 6-26 wherein the development of a shell surrounding a germinal disk is described. See also in the specification page 8, lines 1-6.

Applicants believe these amendments overcome the rejections based on lack of written description and respectfully request withdrawal of these rejections and allowance of amended claims 59, 64 and 65 and dependent claims 60-63.

35 U.S.C. § 112, second paragraph

Claims 59-65 and 77 are rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 77 is canceled herein without prejudice, thereby rendering this rejection moot as it applies to this claim. Thus, applicants request withdrawal of this rejection.

Claims 59, 64 and 65 are amended herein by deleting the problematic language and substituting therefor language that more clearly recites the relationship between the calcified shell and the enclosed female pronucleus which is joined after oviposition with a male pronucleus. The joined female pronucleus and male pronucleus develop into a zygote and embryo in the shell.

Applicants believe these amendments overcome the rejections based on indefiniteness and respectfully request withdrawal of these rejections and allowance of amended claims 59, 64 and 65 and dependent claims 60-63.

35 U.S.C. § 102

Claims 59-80 remain rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by

Johnston (1998 *Poultry Science*, Vol. 77, page 142). Specifically, the Office Action states that the method used to make the egg of Johnston is identical to the method disclosed in the instant specification. The Office Action goes on to state that the egg taught by Johnston is capable of hatching which is all that is required in the claims and equivalent to the teachings in the specification. The Office Action also states that the instant specification does not teach maintaining the egg until hatch.

Johnston et al. (the cited abstract) does not teach an oviposited avian egg comprising an embryo and a shell, wherein the shell is deposited around a female pronucleus before the female pronucleus joins a male pronucleus and the embryo develops from the joining of the female pronucleus and the male pronucleus in the shell, wherein the embryo has fewer than 30,000 cells and can develop in the shell and hatch as a live chick.

Johnston ("In Vitro Sperm Binding, Penetration, and Fertilization of Recently Oviposited Chicken Eggs," Thesis, Graduate School of Clemson University, December, 1998) (Reference "AM," cited in Form PTO 1449 of the Information Disclosure Statement) corresponds to and elaborates on the abstract. Johnston teaches the fertilization of the egg only after it has been removed from the shell. Johnston also teaches that the ovum, after removal from the shell, was treated by mild hydrolysis of the OPL with 0.01 N HCl. Further, Johnston teaches that the *in vitro* fertilized oocytes were subsequently cultured in a medium of thin egg albumen and sterile PBS. Therefore, Johnston creates a very different composition of matter than claimed by applicants.

Johnston does not teach that the embryo develops from the joining of the female pronucleus and the male pronucleus in the shell that deposited around the female pronucleus before the female pronucleus joins a male pronucleus. Indeed, Johnston was trying to accomplish what applicants did accomplish. In doing so, Johnston created a much more complicated composition of matter comprising an *in vitro* fertilized ovum, removed from the shell, that was treated by mild hydrolysis of the OPL with 0.01 N HCl and cultured *in vitro* in medium of thin egg albumen and sterile PBS. Applicants have created a simpler and more natural composition of matter by utilizing the shell deposited around the female pronucleus

before the female pronucleus joins a male pronucleus and simply joining the male pronucleus with the female pronucleus.

The Johnston method only alleges fertilization of an egg that was removed from the shell and cultured *in vitro*. It is clear that Johnston did not place any of the embryos back into egg shells and certainly not into the shell that deposited around the female pronucleus before the female pronucleus joined the male pronucleus. Moreover, contrary to the Office Action's allegation that the instant specification does not teach maintaining the egg until hatch, applicants respectfully point out that the specification does so. See in the specification page 10, line 15 to page 11, line 24.

Therefore, Johnston does not anticipate the claims. Applicants, therefore, respectfully request that this rejection be withdrawn.

Finally, the pending claims also require that the embryo has fewer than 30,000 cells and can develop in the shell and hatch as a live chick. The Office Action states that the embryos created by Johnston can hatch as a live chick. This conclusion is not supported by any of the art cited in the Office Action. Indeed, the art cited in the Office Action specifically does not support this notion since Johnston, as is clear from the Johnston Thesis, was only able to create very early *in vitro* embryos when their goal was to create and develop avian embryos. Indeed the Johnston abstract states "[w]e are developing a system to *in vitro* fertilize, and develop avian embryos from recently oviposited eggs" (emphasis added). The Johnston abstract and the Johnston Thesis on pages 39-43 and Table 3 show that Johnston was only able to create very early embryos that ceased to proliferate. This is in contrast to applicants' claimed invention where the embryos develop in the shell and hatch as a live chick.

Thus, Johnston does not anticipate the claimed invention and removal of the rejection on this basis is respectfully requested.

Claims 66-77 are canceled herein without prejudice to expedite prosecution of this application. Thus, rejection of these claims based on Naito is rendered moot. Therefore, applicants respectfully request withdrawal of this rejection.

35 U.S.C. § 103

Claims 59-80 remain rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Johnston in view of Goldberg (1992, *Ped Research*, Vol. 32, pg 23-26). Goldberg, is a paper related to the study of cardiac teratogenicity of dichloroethylene in a chick model. Goldberg is looking at something completely different from the claimed invention and does not cure the deficiencies of Johnston noted above. Applicants, therefore, respectfully request that this rejection be withdrawn.

As noted above, Johnston ("In Vitro Sperm Binding, Penetration, and Fertilization of Recently Oviposited Chicken Eggs," Thesis, Graduate School of Clemson University, December, 1998) (Reference "AM," cited in Form PTO 1449 of the Information Disclosure Statement) corresponds to and elaborates on the abstract. Johnston teaches the fertilization of the egg only after it has been removed from the shell. Johnston also teaches that the ovum, after removal from the shell, was treated by mild hydrolysis of the OPL with 0.01 N HCl. Further, Johnston teaches that the *in vitro* fertilized oocytes were subsequently cultured in a medium of thin egg albumen and sterile PBS. Therefore, Johnston creates a very different composition of matter than claimed by applicants.

Johnston and Goldberg do not teach or suggest that the embryo develops from the joining of the female pronucleus and the male pronucleus in the shell that deposited around the female pronucleus before the female pronucleus joins a male pronucleus. Indeed, Johnston was trying to accomplish what applicants did accomplish. In doing so, Johnston created a much more complicated composition of matter comprising an *in vitro* fertilized ovum, removed from the shell, that was treated by mild hydrolysis of the OPL with 0.01 N HCl and cultured *in vitro* in medium of thin egg albumen and sterile PBS. Applicants have created a simpler and more natural composition of matter by utilizing the shell deposited around the female pronucleus before the female pronucleus joins a male pronucleus and simply joining the male pronucleus with the female pronucleus. Goldberg adds nothing to cure the Johnston deficiencies.

The Johnston method only alleges fertilization of an egg that was removed from the shell and cultured *in vitro*. It is clear that Johnston did not place any embryos back into egg shells and certainly not into the shell that deposited around the female pronucleus before the female

pronucleus joined the male pronucleus. Moreover, contrary to the Office Action's allegation that the instant specification does not teach maintaining the egg until hatch, applicants respectfully point out that the specification does so. See in the specification page 10, line 15 to page 11, line 24. Therefore, Johnston does not anticipate the claims. Goldberg adds nothing to the deficiencies of Johnston.

Finally, the pending claims also require that the embryo has fewer than 30,000 cells and can develop in the shell and hatch as a live chick. The Office Action states that the embryos created by Johnston can hatch as a live chick. This conclusion is not supported by any of the art cited in the Office Action. Indeed, the art cited in the Office Action specifically does not support this notion since Johnston, as is clear from the Johnston Thesis, was only able to create very early *in vitro* embryos when their goal was to create and develop avian embryos. Indeed the Johnston abstract states "We are developing a system to in vitro fertilize, and develop avian embryos from recently oviposited eggs" (emphasis added). The Johnston abstract and the Johnston Thesis on pages 39-43 and Table 3 show that Johnston was only able to create very early embryos that ceased to proliferate. This is in contrast to applicants' claimed invention where the embryos develop in the shell and hatch as a live chick. Goldberg adds nothing to cure the Johnston deficiencies.

Applicants have created an innovative composition of matter, providing early avian embryos, that was desired but not accomplished or suggested by the art. Indeed, the claimed novel composition is efficiently derived and is the result of an efficient breeding method that can revolutionize poultry breeding processes. In addition, the large number of early embryos in a shell that can be produced by the methods associated with the claimed invention can be utilized for high throughput transgenesis. In other words, the compositions of this invention can be created in large numbers and, thus, can be engineered in large numbers to produce a desired transgenic avian. Thus, the invention provides major advantages to the poultry industry that were desired but unobtainable from prior art methods.

Thus, Johnston and Goldberg do not render obvious the claimed invention, and removal of the rejection on this basis is respectfully requested.

Pursuant to the above amendments and remarks, reconsideration and allowance of the pending claims are believed to be warranted, and such action is respectfully requested. The Examiner is invited to directly contact the undersigned if such contact may enhance the efficient prosecution of this application to issuance.

Credit Card Payment Form PTO-2038 authorizing payment in the amount of $1,390.00 (representing a five-month extension of time fee in the amount of $1,005.00 and a Request for Continued Examination (RCE) fee in the amount of $385.00—small entity) is enclosed. This amount is believed to be correct; however, the Commissioner is hereby authorized to charge any deficiency or to credit any overpayment to Deposit Account No. 14-0629.

Respectfully submitted,

NEEDLE & ROSENBERG, P.C.

Bruce H. Becker, M.D.
Registration No. 48,884

NEEDLE & ROSENBERG, P.C.
Customer No. 23859
678-420-9300 (Tel)
678-420-9301 (Fax)

CERTIFICATE OF MAILING UNDER 37. C.F.R. 1.8

I hereby certify that this correspondence, including any items indicated as attached or included, is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Mail Stop RCE, Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450, on the date indicated below.

Bruce H. Becker, M.D. — Date: 9/20/04